

Remarks

The Non-Final Office Action dated November 9, 2010, has been reviewed and the above-amendments and following remarks are made in response thereto. Claims 1-14 are pending with Claims 15-23 previously cancelled. Claim 14 is amended. Applicants submit that the claim amendments do not introduce any new matter. In view of the following remarks, Applicants respectfully request reconsideration of this application and timely allowance of the pending claims.

Rejections under 35 U.S.C. § 103

Claims 1-14 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Samejima *et al.* (EP 0077956) ("*Samejima*") in view of Berger *et al.* (US 4,470,975) ("*Berger*") (Office Action at pages 2-5). Applicants respectfully traverse this rejection for at least the reasons as set forth below.

To establish *prima facie* obviousness under 35 U.S.C. §103, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). This principle of U.S. law regarding obviousness was not altered by the recent Supreme Court holding in *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 82 USPQ2d 1385 (2007). In *KSR*, the Supreme Court stated that "Section 103 forbids issuance of a patent when 'the differences between the subject matter sought to be patented and the prior art are such the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.'" *KSR*, 127 S.Ct. at 1734.

The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3) the level of skill in the art. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966). See also *KSR*, 127 S.Ct. at 1734, 82 USPQ2d at 1391 ("While the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls.") The Court in *Graham* noted that evidence of secondary considerations, such as commercial success, long felt but unsolved needs, failure of others, etc., "might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." 383 U.S. at 18, 148 USPQ at 467. Furthermore, the Court in *KSR* took the opportunity to reiterate a second long-standing principle of U.S. law: that a holding of obviousness requires the fact finder (here, the Examiner),

to make explicit the analysis supporting a rejection under 35 U.S.C. 103, stating that "rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *Id.* at 1740-41, 82 USPQ2d at 1396 (citing *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)). The Supreme Court in *KSR* stated that "a court *must* ask whether the improvement *is more than* the predictable use of prior art elements according to their established functions." *KSR* at 1740 (emphasis added). As such, in addition to showing that all elements of a claim were known in the prior art and that one of skill had a reason to combine them, the Office must also provide evidence that a reasonable expectation of success existed. MPEP 2143.02.

While the *KSR* Court rejected a rigid application of the teaching, suggestion, or motivation ("TSM") test in an obviousness inquiry, the Court acknowledged the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" in an obviousness determination. *KSR*, 127 S. Ct. at 1731. The Court indicated that there is no necessary inconsistency between the idea underlying the TSM test and the Graham analysis." *Id.* As long as the test is not applied as a "rigid and mandatory" formula, that test can provide "helpful insight" to an obviousness inquiry. *Id.* "Thus, in cases involving new compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound." *Takeda v. Alphapharm*, 492 F.3d 1350, 1357 (Fed. Cir. 2007).

The mere fact that prior art may be modified to produce the claimed product does not make the modification obvious unless the prior art suggests the desirability of the modification. *In re Fritch*, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992); see, also, *In re Papesh*, 315 F.2d 381, 137 U.S.P.Q. 43 (CCPA 1963). In addition, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

In addition, a "combination of known elements would have been *prima facie* obvious if an ordinarily skilled artisan would have recognized an apparent reason to combine those elements and would have known how to do so." Examination Guidelines Update: Developments in the Obviousness Inquiry After *KSR v. Teleflex*, 75 Fed. Reg. 53643, 53659 (Sep. 1, 2010) (citing *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335 (Fed. Cir. 2009) (emphasis added)).

The Examiner asserts that by combining *Berger's* method of removing fluid or edema by diverting water elimination from the renal route to the gastrointestinal route with *Samejima's* enteric coated microcapsules, one of ordinary skill would have had a reasonable expectation of success. Office Action at page 5. Specifically, the Examiner states that "both *Samejima* and *Berger* teaches a composition that can be used in the same [field] of endeavor, such as successfully removing excess body fluids or water by administering an effective amount of a water-soluble polymer to the host." *Id.*

As an initial matter, Applicants respectfully point out that the polymers of the claimed methods are not water-soluble, as the Examiner states in the above-quoted passage. Rather, the polymers of the claimed methods are "water-absorbent . . . capable of absorbing at least 10 times its weight in physiological saline". See pending claim 1 (previously amended). In addition, one of ordinary skill in the art would not be motivated to combine *Samejima* and *Berger*. Even if *Samejima* and *Berger* were combined, the combination would destroy the claimed function of the presently claimed invention, since an effective amount a water-absorbent polymer would not be delivered to the intestinal tract and a fluid overload state would not be treated as claimed. Accordingly, the Office Action's assertion that combining *Samejima* and *Berger* to arrive at the claimed method fails to set forth a *prima facie* case of obviousness, as further described below.

Applicants submit that *Samejima* describes enterically coated microcapsules that are used to deliver an "active component (core material)" (e.g., pharmaceutical compounds) to the intestinal tract. *Samejima*, page 2, lines 16-20; page 3, lines 17-19. Notably, *Samejima* teaches enteric microcapsules having coating walls consisting essentially of ethylcellulose and an enteric polymeric material. *Samejima*, page 1, lines 3-9; page 4, line 4 – page 5, line 8. Upon reaching the intestinal tract, however, the enteric microcapsules do not break up, but rather "the microcapsules become porous [thus] liquid in [the] intestinal tract can easily penetrate into the microcapsules and thereby the release of active component is promoted." *Samejima* at page 12, lines 1-4; see also *Samejima* at page 12, lines 12-15 ("the enteric polymer material in the ethylcellulose coating walls is rapidly dissolved in [the] intestinal tract to make the coating walls porous"). When the microcapsules with coating walls of ethylcellulose and enteric polymer materials have a core material that additionally includes a water-swellaable polymer material as an excipient with the active compound, "the water-swellaable polymer material absorbs the liquid [from the intestinal tract] and swells [causing] the core material [to] finely crack and thereby release of the active compound is further promoted." *Samejima* at

page 12, lines 10-20. Accordingly, *Samejima* does not teach that the water-swellaable polymer material is released into the intestinal tract, just that the active compound, not the water-swellaable polymer, is further released. See *id.*

In addition, and as the Office Action acknowledges, *Samejima* does not teach water-swellaable polymers as active compounds. See *Samejima* at page 10, line 9 - page 11, line 22 (listing active compounds suitable for use with the disclosed microcapsules). Instead, *Samejima* teaches only that the water-swellaable polymer material allows the core material to crack, which then permits intestinal fluid to enter the core material and dissolve the *active agent*. See *Samejima* at page 12, lines 17-23. Thus, the water-swellaable polymer is not released from the porous shell as the polymer is not soluble. See *id.* Accordingly, *Samejima* does not teach the use of absorbent polymers as claimed. In addition, as the Office Action acknowledges, "*Samejima* fails to teach fluid overload state such as congestive heart failure, renal diseases, or edema". See Office Action at page 4.

Berger does not remedy the deficiencies of the disclosures made in *Samejima*. Applicants submit that *Berger* discloses diverting water elimination from the renal route to the gastrointestinal route by orally administering certain insoluble hydrophilic cross-linked polysaccharides. *Berger* Abstract. In particular, *Berger* discloses administering polysaccharide polymers (such as Sephadex) orally as a mixture with food (see *Berger* at Examples 1-3, 5-7) or orally as a suspension in mineral oil (see *Berger* at Example 4). *Berger* does not teach direct delivery of water-absorbent polymers to the intestinal tract.

Applicants submit that *Samejima*, singly or in combination with *Berger*, fails to disclose or suggest all of the limitations of the pending claims. In particular, Applicants submit that pending claim 1 (from which pending claims 2-14 depend) is directed to a method for treating a fluid overload state by directly delivering to the intestinal tract of the host an effective amount of a water-absorbent polymer, wherein the water-absorbent polymer is not directly exposed to the stomach prior to delivery to the intestinal tract. Given that *Samejima* in view of *Berger* fails to provide a method for treating a fluid overload state by directly delivering to the intestinal tract of the host an effective amount of a water-absorbent polymer, wherein the water-absorbent polymer is not directly exposed to the stomach prior to delivery to the intestinal tract, they cannot obviate the present claims.

Accordingly, for the above-mentioned reasons, Applicants respectfully request that the rejection of claims 1-14 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

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Conclusion

Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same. The Examiner is respectfully requested to telephone the undersigned to assist in any way in expediting prosecution of this application. The Commissioner is authorized to charge any underpayment of fees or credit any overpayment of fees to Deposit Account No. 02-1818 (order no. 3716444.00011) for any matter in connection with this response.

Respectfully submitted,
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